DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

TomTec Imaging Systems, GmbH
% Ms. Christine Klein
RA Specialist
Edisonstrasse 6
Unterschleissheim, Bavaria D-85716
GERMANY

February 13, 2015

Re: K150122
Trade/Device Name: Tomtec Arena TTA2
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 15, 2015
Received: January 20, 2015

Dear Ms. Klein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
~~K151501122~~ K150122

Device Name
TomTec-Arena TTA2

Indications for Use *(Describe)*
Indications for use of TomTec-Arena software are quantification and reporting of cardiovascular, fetal, and abdominal structures and function of patients with suspected disease to support the physicians in the diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# Traditional 510(k) Summary

## I. Submitter

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Contact Person: Mrs. Christine Klein
Date Prepared: 2015-01-22

## II. Device

Name of Device: TomTec-Arena TTA2
Common or Usual Name: Image Review and Quantification Software
Classification Name: Picture Archiving and communications system
Regulatory Class: 2
Product Code: LLZ

## III. Predicate Device

| | | |
|---|---|---|
| Predicate Device 1 | K132544 | TomTec-Arena 1.0 |
| Predicate Device 2 | K110667 | Image-Arena 4.5 |

## IV. Device Description

TomTec-Arena™ is a clinical software package for reviewing, quantifying and reporting digital medical data. The software is compatible with different TomTec Image-Arena™ platforms and TomTec-Arena Server©, their derivatives or third party platforms.
Platforms enhance the workflow by providing the database, import, export and other services. All analyzed data and images will be transferred to the platform for archiving, reporting and statistical quantification purposes.

TomTec-Arena™ TTA2 consists of the following optional modules:

- Image-Com
- 4D LV-Analysis and 4D LV-Function
- 4D RV-Function

- 4D Cardio-View
- 4D MV-Assessment
- Echo-Com
- 2D Cardiac-Performance Analysis
- 2D Cardiac-Performance Analysis MR
- 4D Sono-Scan
- Reporting
- Worksheet
- TomTec-Arena Client

## V. Indications for use

Indications for use of TomTec-Arena software are quantification and reporting of cardiovascular, fetal, abdominal structures and function of patients with suspected disease to support the physicians in the diagnosis.

There is only a small change for clarification in the notation of the indications for use which do not alter the intended therapeutic / diagnostic effect and do not affect the safety and effectiveness of the device.

## VI. Comparison of technology characteristics with the predicate device

The Subject Device “TomTec-Arena TTA2” contains modules for analysis of medical studies containing multimodal and multidimensional medical data.

In the actual submission the new modules Reporting and Worksheet are dissolved away from the module Image-Com as independent modules. These functions were also available in the predicate device 1 TomTec-Arena (K132544) imbedded in the module Image-Com. The TomTec-Arena Client functionality has the same technological characteristics as the Image-Arena module of Predicate device 2 (K110667).
For maintenance, all modules of the subject device have been adapted for bug fixing and customer feedback reasons.
Two kinds of changes have been applied to the subject device: Minor changes for operability enhancements or to assure guideline and standard conformance and feature changes of a larger scope. The newly feature changes encompass the Quality Seal (light), cardiac catheterization measurements based on XA images and measurements of the exam type echo. The feature modifications represent a repackaging or new appearance of existing technology to meet the needs of clinical use cases or guideline conformance. Overall, there are no differences in

technological characteristics that raise new or different questions of safety and effectiveness. For detailed information please refer to the attached list of changes.

## VII. Performance Data

### Discussion according non-clinical performance data testing

Testing was performed according to internal company procedures. Software testing and validation were done at the module and system level according to written test protocols established before testing was conducted.
Testing for the newly added feature changes was performed according to the Test Planning. Test results were reviewed by designated technical professionals before software proceeded to release. All requirements have been verified by tests or other appropriate methods.

The V&V summary (VVS_TomTec-Arena_TTA2_Rev01) lists all test reports in the reference table in chapter 1.1:
The catheterization measurements were tested in dedicated XA test reports [105] (page 3701-3745 serial numbering 510(k)) and [206] (page 4063-4076 serial numbering 510(k)),
the XA calibration in test report [212] (page 4183-4204 serial numbering 510(k)), chapter 4.1.2 (page 4192 serial numbering 510(k)).
The quality seal light was tested in test report [212] (page 4183-4204 serial numbering 510(k)), chapter 4.1.3 (page 4195 serial numbering 510(k)).
The echo exam types were tested in test report [107] (page 3746-3831 serial numbering 510(k)). The ‘change tracking’ column indicates changed and ‘new’ measurements to be tested.

Expected results and acceptance (pass/fail) criteria have been defined in all test protocols to ensure that the subject device is safe and effective.
All deviations have been reviewed and classified in chapter 3.7 bugfix verification of the V&V summary. Also, the further handling of the issues is defined.

The incorporated OTS Software is considered validated either by particular tests or implied by the absence of OTS SW related abnormalities during all other Verification & Validation activities.
The summary conclusions state that:

- all automated tests were reviewed and passed
- feature complete test completed without deviations
- functional tests are completed
- measurement verification is completed without deviations
- all non-verified bugs have been evaluated and are rated as minor deviations. They are deferred to the next release.

**Discussion according clinical performance data testing**
Substantial equivalence determination of this subject device was not based on clinical data or studies.
The overall product concept was clinically accepted and supports the conclusion that the device is as safe as effective, and performs as well as or better than the predicate device.

A clinical evaluation following the literature route based on the assessment of benefits, associated with the use of the device, was performed. The clinical evaluation shows that the published data are relevant and applicable to the relevant characteristics of the device under assessment and the medical procedure for which the device is intended.

Risk analysis aspects (including cyber security) were treated in the risk management report. Based on this document the existing applied methods in the literature and the newly described techniques of the product (which are considered in the risk analysis) were evaluated.
No further risks were identified.

## VIII. Conclusions

**Conclusion from the analysis of the literature review**

- The Risk-Benefit Assessment concludes that the benefit is superior to the risk, whereas the risk is low. The product TomTec-Arena is therefore harmless for patient and user and the advantages overbalance the probable risks of injury or illness for the patient.
- The data are sufficient to demonstrate compliance with the essential requirements covering safety and performance of the device in question under normal conditions of use.
- The claims made in the device labelling are substantiated by the clinical data.

**Test Conclusions of non-clinical and clinical performance data**
The overall product concept was clinically accepted and test results support the conclusion, that the device is as safe as effective, and performs as well as or better than the predicate device.

No reportable events or problems for the predicate device exist.

February 11, 2015

J. Waldinger
COO